Remarks

I. Status of the Claims

Claims 1-34 are pending in the present application, with claims 1 and 2 being the independent claims.

II. Summary of the Office Action

In the Office Action dated November 20, 2000, the Examiner has made two objections to the specification and three rejections of the claims. Applicants respectfully offer the following remarks to overcome or traverse each of the rejections.

III. The Objection for Failure to Comply With Sequence Listing Requirements is Traversed

In the Office Action at page 2, the Examiner has objected to the specification for allegedly failing to comply with the sequence listing requirements under 37 C.F.R. §§ 1.821-1.825. Applicants respectfully traverse this rejection.

In making this objection, the Examiner states that the present application fails to comply with the sequence listing requirements because "the sequence comprising the plasmid pAH102.4 in the specification and claim 22 has not been disclosed, and has not been given an accompanying SEQ ID NO." Office Action at page 2, lines 10-11. Applicants respectfully disagree with this statement. Under the sequence disclosure rules of 37 C.F.R. §§ 1.821-1.825, a sequence listing and assignment of a SEQ ID NO: is only necessary when the specification discloses "an unbranched sequence of ten or more nucleotides." 37 C.F.R.

§ 1.821(a). The nucleic acid molecule designated as pAH102.4 is not described or claimed in the form of "an unbranched sequence of ten or more nucleotides." Instead, this molecule is described in the form of a physical restriction map of the molecule (*see* Figure 1 of the present specification). As the Federal Circuit has held, a suitable description for nucleic acid molecule, as an alternative to recitation of the nucleotide sequence, is to provide a precise definition by *structure* of the molecule. *See Regents of Univ. of Calif. v. Eli Lilly & Co.*, 119 F.3d 1559, 1566 (Fed. Cir. 1997) (citing *Fiers v. Revel*, 984 F.2d 1164, 1171 (Fed. Cir. 1993). Thus, the alternative description of plasmid pAH102.4 in the form of a physical restriction map of this molecule suitably describes this molecule, and it is not necessary for a recitation of the nucleotide sequence of this molecule to be included in the present specification. Since this nucleotide sequence has not been (and need not be) included within the present disclosure, Applicants respectfully assert that the present specification is in full compliance with the sequence listing rules under 37 C.F.R. §§ 1.821-1.825.

In view of the foregoing remarks, Applicants respectfully assert that the objection to the specification for failure to comply with the sequence listing rules, and the Notice to Comply upon which this objection is based, have been made in error. Reconsideration and withdrawal are respectfully requested.

IV. The Objection Relating to Deposit of Biological Materials is Accommodated

In the Office Action at pages 2-3, the Examiner has noted that certain biological materials disclosed in the present application (*i.e.*, the vector pAG102.4 recited in claim 22) have been deposited, and has required compliance with the rules relating to the deposit of

biological materials under 37 C.F.R. §§ 1.801-1.809. As noted in the specification at page 18, lines 23-27, the recombinant host cell comprising pAH102.4, *E. coli* STBL2(pAH102.4), was deposited on March 26, 1997, with the Collection, Agricultural Research Culture Collection (NRRL), 1815 North University Street, Peoria, Illinois 61604 USA, as Deposit No. NRRL B-21674. The NRRL is a depository that fully complies with the requirements of the Budapest Treaty, as discussed in detail on the web site of this depository *at* http://nrrl.ncaur.usda.gov/arspatcc.htm. Hence, Applicants hereby state that the deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, and all restrictions on the availability to the public of the material so deposited will be irrevocable upon the granting of a patent from the present application.

In view of the foregoing remarks, Applicants respectfully assert that the present application is in full compliance with the requirements under 37 C.F.R. §§ 1.801-1.809 concerning the deposit of biological materials. Reconsideration and withdrawal of the objection are therefore respectfully requested.

V. The Rejections Under 35 U.S.C. § 112, Second Paragraph, Are Traversed

In the Office Action at pages 4-5, the Examiner has rejected claims 1-34 under 35 U.S.C. § 112, second paragraph, for alleged indefiniteness. Applicants respectfully traverse this rejection.

In making this rejection, the Examiner first contends that the metes and bounds of the term "derivatives thereof" recited in claims 1 and 2 are unclear. Applicants respectfully

disagree with this contention. At several locations in the specification, specific non-limiting examples of"derivatives" of nucleotides suitable for use in the present invention are provided. For example, substituted deoxy-, and dideoxyribonucleotides, are described in the specification as being "derivatives" of nucleotides that are suitable for use in accordance with the claimed invention. *See, e.g.*, specification at page 5, lines 22-25; at page 10, lines 18-24; and in claim 18 as originally filed. Hence, the specification contains adequate description of the meaning of the term "derivatives" as that term is used in claim 1 and 2.

The Examiner also contends that the term "substantially identical" in claims 1 and 2 is unclear. Applicants respectfully disagree with this contention. This term is defined in detail in the present specification:

> By "substantially identical in base composition" is meant that the top and bottom strands of the repeat-containing sequence are about 80%, preferably at least about 90%, more preferably at least about 95%, still more preferably at least about 98% or about 99%, and most preferably at least about 100%, identical in base composition. Although substantially identical base compositions include palindromic sequences, the order of the sequence in the top and bottom strand need not be the same according to the invention.

Specification at page 8, lines 7-13. Thus, the specification contains complete definition of the term "substantially identical" as that term is used in claim 1 and 2.

As the Board has held:

> [35 U.S.C. § 112, second paragraph] merely requires that the claims set forth and circumscribe a particular area with a reasonable degree of precision and particularity. The definiteness of the claim language employed must not be analyzed in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one having ordinary skill in the pertinent art.

Ex parte Moelands, 3 USPQ2d 1474, 1476 (Bd. Pat. App. Int. 1987) (citing *In re Moore*, 439 F.2d 1232 (C.C.P.A. 1971). As noted above, the terms "derivatives" and "substantially identical" are either described using a number of non-limiting examples ("derivatives"), or are fully defined in the specification ("substantially identical"). Thus, Applicants respectfully assert that one of ordinary skill could easily determine the metes and bounds of these terms as they are used in claims 1 and 2, by simply reading these terms in view of the present disclosure as is required under *Moelands*. Hence, claims 1 and 2 fully comport with the requirements of 35 U.S.C. § 112, second paragraph, as interpreted under *Moelands* and *Moore*.

In view of the foregoing remarks, Applicants respectfully assert that the present claims particularly point out and distinctly claim the subject matter regarded by Applicants as the invention. Reconsideration and withdrawal of the rejection of claims 1-34 under 35 U.S.C. § 112, second paragraph, are respectfully requested.

VI. The Rejection Under 35 U.S.C. § 112, First Paragraph, Is Traversed

In the Office Action at pages 5-6, the Examiner has rejected claims 1-34 under 35 U.S.C. § 112, first paragraph, for lack of sufficient written description that would convey to one of ordinary skill that Applicants had possession of the claimed invention as of the filing date of the present application. Applicants respectfully traverse these rejections.

Citing the revised guidelines for examining applications for compliance with the written description requirement, issued in December 1999, the Examiner contends that:

> [t]he specification and claims do not indicate what distinguishing attributes are concisely shared by members of the genus

> comprising *derivatives* of nucleotides, nor of the genus comprising *substantially identical* nucleotide compositions of $(X_1X_2)_n$ (and its complement, $(Y_1Y_2)_n$), or substantially identical nucleotide compositions of $(X_1X_2)_nA_m$ (and its complement, $B_m(Y_1Y_2)_n$). The specification does not place any limit on the number of nucleic acid derivatives, substitutions, deletion, insertions and/or additions which correspond to such genera. Thus, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted . . . . Since the disclosure fails to describe the common attributes or characteristics concisely identifying members of the proposed genera, and because the genera are highly variant, the description provided is insufficient. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genera claimed.

Office Action at page 5, fourth paragraph, lines 2-10 and at page 6, lines 4-7. Applicants respectfully disagree with these contentions.

From the emphasis placed on the words "derivatives" and "substantially identical" in the above excerpt of the Office Action, it appears that the Examiner is basing this rejection on the alleged lack of a concise definition of these two terms in claims 1 and 2 (and thus in the remaining claims depending therefrom). Specifically, the Examiner apparently is contending that precise distinguishing attributes of "derivatives" of nucleotides and "substantially identical" nucleotide compositions are allegedly lacking from the present specification, and that this allegedly insufficient description would lead one of ordinary skill to conclude that Applicants did not have possession of the invention at the filing date of the present application. Applicants respectfully disagree. As noted above, the terms "derivatives" and "substantially identical" are fully exemplified and/or defined in the specification, in such a way as to provide an adequate representative number of species of the genera encompassed by claims 1 and 2 as currently presented. Specifically, one of ordinary

skill reading claims 1 and 2 in view of the disclosure in the specification, particularly at pages 5-10 and throughout the Examples, could readily determine whether a given nucleic acid molecule falls within the scope of claims 1 and 2. Moreover, the present specification provides detailed examples of specific nucleic acid molecules possessing the physical and/or structural characteristics of the molecules encompassed by claims 1 and 2, by specifying, *inter alia*: (a) nucleotides (and derivatives thereof) that are preferably used in the claimed nucleic acid molecules (*see* specification at pages 5 and 10); (b) preferred numbers of nucleotides used in the nucleic acids (*see* specification at pages 5 and 9-10); and (c) preferred restriction sites used in the nucleic acids (*see* specification at pages 11-13). Finally, the present specification specifically describes at least four exemplary nucleic acid molecules having these desired physical characteristics (SEQ ID NOs: 1-4; *see* specification at pages 8, 17, and 21-22), as well as a deposited plasmid (pAH102.4) comprising such an exemplary nucleic acid molecule.

Applicants wish to remind the Examiner that "[a]dequate description under the first paragraph of 35 U.S.C. 112 does not require *literal* support for the claimed invention . . . . the observation of a lack of literal support does not, in and of itself, establish a *prima facie* case for lack of adequate descriptive support under the first paragraph of 35 U.S.C. 112." *Ex parte Parks*, 30 USPQ2d 1234, 1236 (Bd. Pat. App. Int. 1994). Instead, the written description requirement of 35 U.S.C. § 112, first paragraph, is met "if the originally-filed disclosure would have conveyed to one having ordinary skill in the art that an [applicant] had possession of the concept of what is claimed," *id.*, *i.e.*, "[i]f a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time

of filing, even if every nuance of the claims is not explicitly described in the specification . . . ." *In re Alton*, 37 USPQ2d 1578, 1584 (Fed. Cir. 1996). An applicant is not required to disclose or provide a working example of every species of a given genus in order to meet the written description requirement of 35 U.S.C. § 112 (*see Parks* and *Alton*), and subject matter that "might fairly be deduced from the original application" is considered to be described in the application as filed. *Acme Highway Products Corp. v. D.S. Brown Co.*, 431 F.2d 1074, 1080 (6th Cir. 1970) (citations omitted), *cert. denied*, 401 U.S. 956 (1971), *followed by Westphal v. Fawzi*, 666 F.2d 575, 577 (C.C.P.A. 1981). Moreover:

> [a] description of a genus of [nucleic acid molecules] may be achieved by means of a recitation of a representative number of [nucleic acid molecules], defined by nucleotide sequence, falling within the scope of the genus . . . .

Regents of Univ. of Calif. v. Eli Lilly & Co., 119 F.3d 1559, 1569 (Fed. Cir. 1997).

As noted above, the present specification describes a number of representative examples of the claimed genus of nucleic acid molecules comprising "derivatives" of nucleotides and "substantially identical" nucleotide compositions, and provides detailed specifications for the physical and/or structural characteristics of other nucleic acid molecules that would fall within the scope of claims 1 and 2. In so doing, the "representative number" standard under *Eli Lilly*, upon which the Written Description Guidelines cited by the Examiner are based, is clearly met by the present specification. Hence, Applicants respectfully assert that the present specification provides sufficient written description to convey to one of ordinary skill that Applicants had possession of the full scope of the claimed invention upon filing of the application.

In view of the foregoing remarks, Applicants respectfully assert that the specification as originally filed fully describes the invention as presently claimed. Reconsideration and withdrawal of the rejection of claims 1-34 under 35 U.S.C. § 112, first paragraph, are therefore respectfully requested.

VII. The Rejection Under 35 U.S.C. § 102(e) Over Singer Is Traversed

In the Office Action at pages 6-7, the Examiner has rejected claims 1-16, 18-21 and 23-34 under 35 U.S.C. § 102(e) as being anticipated by Singer, U.S. Patent No. 5,824,787 (Doc. "A" on the Form PTO-892 attached to Paper No. 6; hereinafter "Singer"). Applicants respectfully traverse this rejection.

Under 35 U.S.C. § 102, a claim can only be anticipated if every element in the claim is expressly or inherently disclosed in a single prior art reference. *See Kalman v. Kimberly Clark Corp.*, 713 F.2d 760, 771 (Fed. Cir. 1983), *cert. denied*, 465 U.S. 1026 (1984); *see also PPG Industries, Inc. v. Guardian Industries Corp.*, 75 F.3d 1558, 1566 (Fed. Cir. 1996) ("[t]o anticipate a claim, a reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter."). In addition, under 35 U.S.C. § 102(b), a claim can only be anticipated by a publication if the publication describes the claimed invention with sufficient detail to place the public in possession of the invention. *See In re Donohue*, 766 F.2d 531, 533 (Fed. Cir. 1985). Moreover, "even if the claimed invention is disclosed in a printed publication, that disclosure will not suffice as prior art if it was not enabling." *Id.* Applicants respectfully assert that Singer does not support a rejection of the invention as presently claimed under 35 U.S.C. § 102(e).

The invention as presently claimed is drawn to certain nucleic acid molecules comprising two or more repeat-containing sequences, wherein the nucleotide compositions of the top strand ("$(X_1X_2)_n$" in claim 1; "$(X_1X_2)_nA_m$" in claim 2) and bottom strand ("$(Y_1Y_2)_n$" in claim 1; "$B_m(Y_1Y_2)_n$" in claim 2) are substantially identical. In contrast, Singer does not disclose such molecules wherein the top and bottom strands have substantially identical base compositions. Although Singer indicates that the top and bottom strands of double-stranded nucleic acid molecules described therein may be *complementary* in base composition (*see* Singer at col. 4, lines 5-9), Singer does not disclose or suggest that the two strands should be substantially identical in base composition. In fact, Applicants note that the molecules specifically exemplified in Example 2 at cols. 11-13 and in Fig. 2 of Singer, and referred to in Singer as "the prototypic embodiment" of the invention disclosed therein (*see* Singer at col. 13, lines 11-12), do *not* contain substantially identical base compositions in the top and bottom strands. Singer therefore fails to expressly or inherently disclose every element of the claimed invention in a way so as to enable one of ordinary skill to make and use the presently claimed invention. Hence, under *Kalman*, *PPG Industries*, and *Donohue*, Singer cannot and does not anticipate the presently claimed invention.

In view of the foregoing remarks, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1-16, 18-21 and 23-34 under 35 U.S.C. § 102(e) over Singer.

IX. Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn.

Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Respectfully submitted,

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